

REMARKS

Formal Matters

Claims 28 and 30 remain pending in this application. Claim 30 is amended. No new matter is added by the amendments. Support for the amendments is found throughout the specification, such as at page 22, lines 17-24; page 31, line 18 to page 33, line 2; and Figure 4.

In view of the Examiner's earlier restriction requirement, applicant retains the right to present withdrawn claims in a divisional application and/or the right to petition for withdrawal of such restriction requirement under 37 CFR 1.143.

Withdrawal of a Claim

Claim 29 was withdrawn from further consideration pursuant to 37 CFR 1.142(b) as drawn to a nonelected invention. Applicants timely traversed the rejection and retain their rights under 37 CFR 1.143 as noted above.

Rejections Withdrawn

Applicants gratefully acknowledge withdrawal of the rejections as stated in the Office Action at pages 2 -3 (paragraphs 5-7).

Rejection Under 35 U.S.C. § 102(b) (Neblock et al.)

The Examiner maintained the rejection of Claim 30 under 35 U.S.C. § 102(b) as allegedly being anticipated by Neblock et al. (Bioconjugate Chem. 3:126-131 (1992), of record). Claim 28 depends from claim 30. Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

Applicants claim a composition comprising a mixture of antibody fragment comprising incorrectly disulfide linked light and heavy chains and antibody fragment comprising correctly disulfide linked light and heavy chains, wherein the purity of the antibody fragment comprising correctly disulfide linked light and heavy chains in the composition is at least about 95%.

Neblock et al. disclose Fab' fragments associated by a thioether linkage to form a F(ab')₂ and that the F(ab')₂ was approximately 93% pure (page 128, col.2 to 129, col. 1). The authors make no suggestion or disclosure regarding the association of light and heavy chains in the composition, much less a suggestion or disclosure that the purity of the antibody fragment comprising correctly disulfide linked light and heavy chains is at least about 95%. Thus, Neblock et al. fail to anticipate applicants' invention. The rejection should be withdrawn, which action is respectfully requested.

Rejection Under 35 U.S.C. § 103(a) (Neblock et al. in view of Shalaby et al.)

Claims 28 and 30 are is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Neblock et al., supra, and further in view of Shalaby et al. (J. Exp. Med. 175:217-225 (1992)). Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

Applicants claim a composition comprising a mixture of antibody fragment comprising incorrectly disulfide linked light and heavy chains and antibody fragment comprising correctly disulfide linked light and heavy chains, wherein the purity of the antibody fragment comprising correctly disulfide linked light and heavy chains in the composition is at least about 95%. Applicants further claim that the antibody fragment binds p185^{HER2}.

The Neblock et al. reference is described above.

Shalaby et al. discloses a humanized bispecific antibody that binds HER2. The reference neither suggests, much less discloses, a composition comprising antibody fragments having incorrectly or correctly disulfide linked light and heavy chains, wherein the purity of the antibody fragment comprising correctly disulfide linked light and heavy chains is at least about 95%. The mere disclosure of HER2 binding of a bispecific antibody by Shalaby et al. fails to cure the deficiency of the Neblock et al. reference. Because neither of the cited references alone or in combination yield applicants' claimed invention, the rejection should be withdrawn, which action is respectfully requested.

SUMMARY

Claims 28 and 30 are pending in the application. Claim 30 is amended. The rejections under Sections 102(b) and 103(a) have been overcome based on the arguments presented herein. Withdrawal of the rejections and allowance of the claims is respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This response/amendment is submitted with a transmittal letter and petition for a three-month extension of time and fees. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

GENENTECH, INC.

By: 

Deirdre L. Conley

Reg. No. 36,487

Telephone No. (650) 225-2066

Date: August 3, 2004

Clean Set of All Pending Claims

August 3, 2004

28. (Previously presented) The composition of claim 30 wherein the antibody fragment binds p185^{HER2}.

30. (Currently Amended) A composition comprising a physiologically acceptable carrier, and a mixture of antibody fragment comprising incorrectly disulfide linked light and heavy chains and antibody fragment comprising correctly disulfide linked light and heavy chains, wherein the purity of the antibody fragment comprising correctly disulfide linked light and heavy chains in the composition is at least about 95%, and wherein the antibody fragment is selected from the group consisting of a F(ab')₂ fragment, Fab fragment, Fab' fragment and linear F(ab')₂ fragment.